

(d) Tolerances contemplated by paragraphs (a) and (b) of this section will in addition to toxicological considerations be conditioned on the availability of a practicable analytical method to determine the pesticide residue; that is, the method must be sensitive and reliable at the tolerance level or in special cases at a higher level where such level is deemed satisfactory and safe in light of the toxicity of the pesticide residue and of the unlikelihood of such residue exceeding the tolerance. The analytical methods to be used for enforcement purposes will be those set forth in the "Pesticide Analytical Manual" (see §180.101(c)). The sensitivities of these methods are expressed in that manual.

Subpart B—Procedural Regulations

§ 180.7 Petitions proposing tolerances or exemptions for pesticide residues in or on raw agricultural commodities or processed foods.

(a) Petitions to be filed with the Agency under the provisions of FFDCA section 408(d) shall be submitted in duplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall be accompanied by an advance deposit for fees described in §180.33. The petition shall state the petitioner's mail address to which notice of objection under FFDCA section 408(g)(2) may be sent. The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(b) Petitions shall include the following information:

(1) An informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition. Both a paper and electronic copy of the summary should be submitted. The electronic copy should be formatted according to the Office of Pesticide Programs' current standard for electronic data submission as specified at <http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm>.

(2) A statement that the petitioner agrees that such summary or any in-

formation it contains may be published as a part of the notice of filing of the petition to be published under FFDCA section 408(d)(3) and as a part of a proposed or final regulation issued under FFDCA section 408.

(3) The name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue.

(4) Data showing the recommended amount, frequency, method, and time of application of the pesticide chemical.

(5) Full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations.

(6) Full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used. (See §180.34 for further information about residue tests.)

(7) Proposed tolerances for the pesticide chemical residue if tolerances are proposed.

(8) Practicable methods for removing any amount of the residue that would exceed any proposed tolerance.

(9) A practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed.

(10) If the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food.

(11) Such information as the Administrator may require to make the determination under FFDCA section 408(b)(2)(C).

(12) Such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

(13) Information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue.

(14) Information concerning any maximum residue level established by the Codex Alimentarius Commission for the pesticide chemical residue addressed in the petition. If a Codex maximum residue level has been established for the pesticide chemical residue and the petitioner does not propose that this level be adopted, a statement explaining the reasons for this departure from the Codex level.

(15) Such other data and information as the Administrator requires by regulation to support the petition.

(16) Reasonable grounds in support of the petition.

(c) The data specified under paragraphs (b)(1) through (b)(16) of this section should be on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by reference to the earlier one.

(d) Except as noted in paragraph (e) of this section, a petition shall not be accepted for filing if any of the data prescribed by FFDCA section 408(d) are lacking or are not set forth so as to be readily understood. The availability to the public of information provided to, or otherwise obtained by, the Agency under this part shall be governed by part 2 of this chapter. The Administrator shall make the full text of the summary referenced in paragraph (b)(1) of this section available to the public in the public docket at <http://www.regulations.gov> no later than publication in the FEDERAL REGISTER of the notice of the petition filing.

(e) The Administrator shall notify the petitioner within 15 days after its receipt of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. If petitioner desires, the petitioner may supplement a deficient petition after notification as to deficiencies. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified.

(f) A notice of the filing of a petition for a pesticide chemical residue tolerance that the Administrator determines has met the requirements of paragraph (b) of this section shall be published in the FEDERAL REGISTER by

the Administrator within 30 days after such determination. The notice shall state the name of the pesticide chemical residue and the commodities for which a tolerance is sought and announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall explicitly reference the specific docket identification number in the public docket at <http://www.regulations.gov> where the full text of the summary required in paragraph (b) of this section is located, and refer interested parties to this document for further information on the petition. The full text of the summary may be omitted from the notice.

(g) The Administrator may request a sample of the pesticide chemical at any time while a petition is under consideration. The Administrator shall specify in its request for a sample of the pesticide chemical, a quantity which it deems adequate to permit tests of analytical methods used to determine residues of the pesticide chemical and of methods proposed by the petitioner for removing any residues of the chemical that exceed the tolerance proposed.

(h) The Administrator shall determine, in accordance with the Act, whether to issue an order that establishes, modifies, or revokes a tolerance regulation (whether or not in accord with the action proposed by the petitioner), whether to publish a proposed tolerance regulation and request public comment thereon under § 180.29, or whether to deny the petition. The Administrator shall publish in the FEDERAL REGISTER such order or proposed regulation. After receiving comments on any proposed regulation, the Administrator may issue an order that establishes, modifies, or revokes a tolerance regulation. An order published under this section shall describe briefly how to submit objections and requests for a hearing under part 178 of this chapter. A regulation issued under this section shall be effective on the date of publication in the FEDERAL REGISTER

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unless otherwise provided in the regulation.

[70 FR 33360, June 8, 2005, as amended at 73 FR 75600, Dec. 12, 2008]

§ 180.8 Withdrawal of petitions without prejudice.

In some cases the Administrator will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a tolerance or the tolerance requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal may be without prejudice to a future filing. A deposit for fees as specified in § 180.33 shall accompany the resubmission of the petition.

[70 FR 33361, June 8, 2005]

§ 180.9 Substantive amendments to petitions.

After a petition has been filed, the petitioner may submit additional information or data in support thereof, but in such cases the petition will be given a new filing date.

[70 FR 33361, June 8, 2005]

§ 180.29 Establishment, modification, and revocation of tolerance on initiative of Administrator.

(a) Upon the Administrator's own initiative, the Administrator may propose, under FFDCA section 408(e), the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance, or a regulation modifying or revoking an existing tolerance or exemption.

(b) The Administrator shall provide a period of not less than 60 days for persons to comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(c) After reviewing any timely comments received, the Administrator may by order establish, modify, or revoke a tolerance regulation, which order and

regulation shall be published in the FEDERAL REGISTER. An order published under this section shall state that persons may submit objections and requests for a hearing in the manner described in part 178 of this chapter.

(d) Any final regulation issued under this section shall be effective on the date of publication in the FEDERAL REGISTER unless otherwise provided in the regulation.

[70 FR 33361, June 8, 2005]

§ 180.30 Judicial review.

(a) Under FFDCA section 408(h), judicial review is available in the United States Courts of Appeal as to the following actions:

(1) Regulations establishing general procedures and requirements under FFDCA section 408(e)(1)(C).

(2) Orders issued under FFDCA section 408(f)(1)(C) requiring the submission of data.

(3) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to establishment, modification, or revocation of a tolerance or exemption under FFDCA section 408(d)(4), or any regulation that is the subject of such an order. The underlying action here is Agency disposition of a petition seeking the establishment, modification, or revocation of a tolerance or exemption.

(4) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to the denial of a petition under FFDCA section 408(d)(4).

(5) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to the establishment, modification, suspension, or revocation of a tolerance or exemption under FFDCA section 408(e)(1)(A) or (e)(1)(B). The underlying action here is the establishment, modification, suspension, or revocation of a tolerance or exemption upon the initiative of EPA including EPA actions pursuant to FFDCA sections 408(b)(2)(B)(v), 408(b)(2)(E)(ii), 408(d)(4)(C)(ii), 408(l)(4), and 408(q)(1).

(6) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to the revocation or modification of a tolerance or exemption under FFDCA section 408(f)(2) for noncompliance with requirements for the submission of data.